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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,619	11/30/2001	Gregory Conn	3298/1H309US2	5770

31846 7590 05/15/2003

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PO BOX 318  
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EXAMINER
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LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 05/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/998,619	CONN ET AL.
	Examiner Samuel W Liu	Art Unit 1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 9 April 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1 and 3-20 is/are pending in the application.

4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,3-9 and 13-20 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) 11  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other.

## **DETAILED ACTION**

Applicants' response filed 9 April 2003 (Paper No. 9) as to cancellation of claim 2 and amendment of claims 1, 3-4, 6, 13 and 15 has been entered. The following Office Action is applicable to the pending claims 1, 3-9 and 13-20.

Please note that the rejection(s) not explicitly stated and/or restated below are withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1 and 2-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and the claims dependent thereto are unclear because the claim fails to indicate steps of the protection as to how the protection is accomplished.

### **Response to the rejection under 35 USC 112, the second paragraph**

The response filed 9 April 2003 requests reconsideration of claim 1 rejection in light of the argument and amendment (see page 8). The applicants' argument has been considered but it is not persuasive. Applicants have not amended claim with respect to lacking indication of step(s) of the claimed protection process in claim 1. The applicants argument that the specification states that protecting free sulphydryl groups of Tn I under reducing conditions

means (see page 8, the second paragraph) is deemed unpersuasive since reciting “under reducing conditions” *per se* does not have an impact on describing what actual step(s) of protection process is.

***Claim Rejection, 35 U.S.C. 101, Double Patenting***

In view of applicants’ abandonment of copending Application No. 09903398, the previous Double Patenting rejection under 35 U.S.C. 101 are withdrawn.

Additionally, upon consideration of applicants’ amendment of claims 1, 4 and 8, the previous provisional rejections, 35 U.S.C. 101, Double Patenting over copending Application Nos: 10287188 and 1025244 are withdrawn.

***Claim Rejections - Provisional Rejection, Obviousness Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-9 and 13-20 of the instant application are provisionally rejected under the judicially created doctrine of double patenting over claims 1-9 and 13-20 of copending Application No. 10287188. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 2 of Application No. 10287188 discloses the common subject matter set forth in the instant claim 1.

Claims 3, 4, 6, 13 and 15 of Application No. 10287188 are obvious variations of claims 3 and 15 of the instant application in that both the claimed methods are directed to the same subject matter, i.e., sulfhydrylation of TnI protein for purifying the soluble protein thereof but differ in the claim scope regarding (i) using sulfhydryl group protecting reagent, i.e., sodium sulfite ( $\text{Na}_2\text{SO}_3$ ) (the current application) or sodium tetrathionate ( $\text{Na}_2\text{S}_4\text{O}_6$ ) (Application 10287188); and (ii) purification of the naturally occurring TnI protein (the instant application) versus the recombinant TnI protein (Application 10287188).

Claim 9 of Application No. 10287188 discloses the same subject matter as that of the current application.

Claims 5, 7-8, 14 and 16-20 of both Application 10287188 and the current application are identical.

Therefore, the claims of the present application are not patentably distinct from the claims of Application No. 10287188.

Claims 1, 2-9 and 13-20 of the instant application are also provisionally rejected under the judicially created doctrine of double patenting over claims 1-9 and 13-20 of copending Application No.10255244. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1 and 2 of Application No. 10255244 discloses the common subject matter set forth in the instant claim 1.

Claims 3, 4, 6, 13 and 15 of Application No. 10287188 are obvious variations of claims 3 and 15 of the instant application in that both the claimed methods are directed to the same subject matter, i.e., sulfitolyzation of TnI protein for purifying the soluble protein thereof but differ in the claim scope regarding (i) using sulfhydryl group protecting reagent, *i.e.*, sodium sulfite ( $\text{Na}_2\text{SO}_3$ ) (the current application) or sodium tetrathionate ( $\text{Na}_2\text{S}_4\text{O}_6$ ) (Application 10255244); and (ii) purification of the naturally occurring TnI protein (the instant application) versus the recombinant TnI protein (Application 10255244).

Claim 5, 7-9, 14 and 16-20 of Application No. 10255244 are word for word identical to claim of 5, 7-8, 14 and 16-20 Application No. 10255244.

Therefore, the claims of the present application are not patentably distinct from the claims of Application No. 10255244.

Response to the Claim Rejections - Provisional Rejection, Obviousness Type Double Patenting

The response filed 9 April 2003 asserts that the applicants' abandonment of the reference applications should obviate the rejections (see page 13). The applicants' argument is unconvincing because, as yet, applicants have not abandoned Application Nos: 10287118 and 10255244 (see also interview summary, Paper No. 11). Thus, the above-stated rejections are maintained.

***Conclusion***

No claims are allowed.

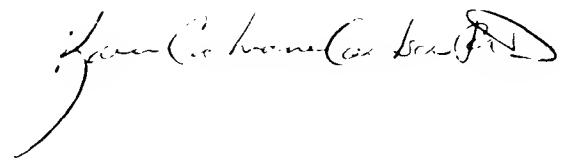
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

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The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

Samuel Wei Liu, Ph.D.

May 12, 2003